FEB 10 2000

K000186

Datex-Ohmeda
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This 510(k) summary of safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 1992.

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|---|---|
| Date: | February 4, 2000 |
| Subject: | 510(k) Summary of Safety and Effectiveness Information for the Datex-Ohmeda INOvent Delivery System |
| Proprietary Name: | Datex-Ohmeda INOvent Delivery System |
| Common Name: | Nitric Oxide Administration Apparatus, Nitric Oxide Analyzer, Nitrogen Dioxide Analyzer, Oxygen Analyzer |
| Classification: | Anesthesiology, Class II - 21CFR 868.5165 Nitric Oxide Administration Apparatus<br>21CFR 868.2380 Nitric Oxide Analyzer<br>21CFR 868.2385 Nitrogen Dioxide Analyzer |
| Predicate Devices: | Datex-Ohmeda INOvent Delivery System Class II - 21CFR 868.5165 Nitric Oxide Administration Apparatus, 21CFR 868.2380 Nitric Oxide Analyzer, 21CFR 868.2385 Nitrogen Dioxide Analyzer<br>Ohmeda 5120 Oxygen Analyzer - Class II - 21CFR868.1720<br>Ohmeda M2100 Air/Oxygen Blender - Class II - 21CFR868.5330<br>Ohmeda Electronic MDM Mixer (Matrx Centurion Mixer) - Class II - 21CFR868.5330 |
| Indications: | The Datex-Ohmeda INOvent delivery system delivers nitric oxide therapy gas into the inspiratory limb of the patient breathing circuit in a way that provides a constant concentration of NO, as set by the user, to the patient throughout the inspired breath. It uses a specially designed injector module which enables the tracking of ventilator waveforms and the delivery of a synchronized and proportional dose of NO. It may be used with most ventilators. It provides continuous on-line integrated monitoring of delivered O2, NO2 and NO, and a comprehensive alarm system. It has an interactive control panel and display that provides a simple to understand interface for operation. It has a battery system that provides up to 30 minutes of uninterrupted nitric oxide delivery in the absence of an external power source. It provides an integrated manual NO delivery system for administration of a fixed concentration of NO/O2 therapy with a resuscitator bag. |
| Standards: | The Datex-Ohmeda INOvent Delivery System was designed to comply with the applicable portions of UL2601-1, 1994, IEC601-1-2 (1993), IEC601-1-4, ASTM F1463-93, CEN475:1995, CGA 626; Compressed Gas Association - Nitric Oxide Specific Gas Connector Specification. |
| Summary: | The Datex-Ohmeda INOvent Delivery System and the currently marketed devices are substantially equivalent in design concepts, technologies and materials. It complies with applicable design and performance standards. Testing demonstrates that the INOvent performs similarly when used in combination with a SensorMedics 3100A High Frequency Oscillatory Ventilator as when used with other previously validated ventilators. Thus, Datex-Ohmeda deems the SensorMedics 3100A compatible with the INOvent. |
| Contact: | The contact person for this 510(k) is Dan Kosednar, Regulatory Affairs Specialist. |

**Datex-Ohmeda**

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 10 2000

Mr. Daniel Kosednar
Date-Ohmeda
Ohmeda Drive
P.O. Box 7550
Madison, WI 53707-7550

Re: K000186
INOvent Delivery System
Regulatory Class: II (two)
Product Code: MRN, MRO, MRP, and MRQ
Dated: January 7, 2000
Received: January 14, 2000

Dear Mr. Kosednar:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4648. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification"(21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597, or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Celia M. Witten, Ph.D., M.D.
Acting Director
Division of Cardiovascular,
Respiratory, and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K000186

Device Name: Datex-Ohmeda INOvent Delivery System

Indications For Use:

The INOvent delivery system delivers nitric oxide therapy gas into the inspiratory limb of the patient breathing circuit in a way that provides a constant concentration of NO, as set by the user, to the patient throughout the inspired breath. It uses a specially designed injector module which enables the tracking of ventilator waveforms and the delivery of a synchronized and proportional dose of NO. It may be used with most ventilators. It provides continuous on-line integrated monitoring of delivered O2, NO2, and NO, and a comprehensive alarm system. It has an interactive control panel and display that provides a simple to understand interface for operation. It has a battery system that provides up to 30 minutes of uninterrupted nitric oxide delivery in the absence of an external power source. It provides an integrated manual NO delivery system for administration of a fixed concentration of NO/O2 therapy with a resuscitator bag.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular, Respiratory, and
Neurological Devices

510(k) Number: K000186

Prescription Use ✓ OR Over-The-Counter Use

(Per 21CFR801.109) (Optional Format 1-2-96)